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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,068

07/19/2007

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12279-162-999

5871

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04/07/2008

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/589,068	LIU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David A. Saunders	1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

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### **CLAIMS PENDING**

Claims 1-13 are pending and under consideration.

### **REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claims 7 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7 “the buffer” lacks antecedent basis in claim 2.

In claims 10 and 11, “after anion exchange” lacks antecedent basis in claims 1 and 2.

In claims 12 and 13, “is recovered” is unclear because claims 1 and 2 have recited nothing about “recovering”.

### **REJECTION(S) UNDER 35 USC 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wan et al (6,177,548).

Wan et al purify humanized monoclonal antibody Hu-901 (a humanized monoclonal antibody is inherently a “recombinant antibody”) by using anion exchange chromatography to remove aggregates. In Example 2, they choose Q-Sepharose FF as

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a resin for production (i.e. “manufacturing”) scale purification (col. 3, lines 20-31). The isoelectric point of Hu-901 has been determined (col. 2, lines 53-55). The pH and salt concentration of the loading buffer are chosen, based upon the known pI value (col. 1, lines 40-67 and col. 2, lines 53-57). The loading buffer and the wash buffer are the same, as shown in Table II. From these considerations claims 1 and 3-4 are anticipated.

The loading and wash buffer of Table II has a salt concentration within the range recited in claim 7. The aggregate levels and the recovery levels recited in instant claims 10-13 are shown in Table III.

Claims 2-10 and 12-13 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Ansaldi et al (6,620,918).

Ansaldi et al purify humanized monoclonal antibodies E25 and E26 (col. 6, lines 52-60) by using anion exchange chromatography to remove dimers and other multimers (i.e. “aggregates”). Note that any humanized monoclonal antibody is inherently a “recombinant antibody”. In Example 1, they choose Q-Sepharose FF as a resin for purification (col. 6, lines 46-47). The isoelectric point of Hu-901 has been determined (col. 6, line 53). The pH of the loading buffer is chosen, based upon the known pI value (col. 5, lines 9-11). The loading buffer is Tris-HCl at pH 8. Separation of monomers from the dimers/multimers can be achieved by the use of a step gradient elution buffer containing 200, 175, 150, or 125 mM NaCl. Ansaldi et al note that this “separation works” (see top row of Table I, for Resin QSFF). From these considerations claims 2-9 are anticipated.

Ansaldi et al disclose that recovery of the antibodies is “typically greater than 90% at greater than 99/5% purity” (col. 9, line 66-col. 10, line 51); thus claims 10 and 12-13 are anticipated.

Claims 2-10 and 12-13 are rejected under 35 U.S.C. 102(b) being anticipated by Ansaldi et al (WO 99/62936).

Ansaldi et al (WO 99/62936) is a document equivalent to Ansaldi et al (6,620,918). The former is cited because of its publication date, which permits it to be

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cited as a 102(b) document. No copy is provided, since the examiner does not have time to copy it and scan it.

## **CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 3/31/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644